



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

September 16, 2003

H.R. 1260

Animal Drug User Fee Act of 2003

*As ordered reported by the House Committee on Energy and Commerce
on September 10, 2003*

SUMMARY

H.R. 1260 would amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration (FDA) to collect fees to cover the cost of expediting the review of new and supplemental animal drug applications and investigational animal drug submissions. Such fees could be collected and made available for obligation only to the extent, and in the amount, provided in advance in appropriation acts.

H.R. 1260 also would require the Secretary of Health and Human Services to submit annual performance and fiscal reports related to the animal drug user fee program to the Congressional committees of jurisdiction.

Because the spending of new fees would lag behind their collection, CBO estimates that implementing H.R. 1260 would reduce net outlays by \$4 million over the 2004-2008 period, assuming the necessary authorities are provided in appropriation acts.

H.R. 1260 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would not affect the budgets of state, local, or tribal governments.

The bill would impose private-sector mandates as defined in UMRA on manufacturers of new animal drugs, by requiring them to pay fees to the Food and Drug Administration. CBO estimates that the direct cost of the mandates would not exceed the annual threshold specified in UMRA (\$117 million in 2003, adjusted annually for inflation) in any of the first five years that the mandates would be effective.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 1260 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars				
	2004	2005	2006	2007	2008
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Collection of FDA User Fees					
Estimated Authorization Level	-5	-8	-11	-11	-14
Estimated Outlays	-5	-8	-11	-11	-14
Spending of FDA User Fees					
Estimated Authorization Level	5	8	11	11	11
Estimated Outlays	3	7	10	10	11
FDA Administrative Expenses					
Estimated Authorization Level	1	*	*	*	1
Estimated Outlays	1	*	*	*	1
Net Effect on Spending by the Food and Drug Administration					
Estimated Authorization Level	1	*	*	*	-2
Estimated Outlays	-1	*	*	*	-2
Note: * = Less than \$500,000.					

BASIS OF ESTIMATE

For this estimate, CBO assumes the bill will be enacted early in fiscal year 2004 and that appropriation acts will provide the necessary authority for fee collection and spending.

Estimated Authorizations

H.R. 1260 would establish a new user fee program to help defray FDA's costs of expediting the review process for animal drugs. CBO estimates that implementing the bill would save \$1 million in 2004 and \$4 million over the 2004-2008 period.

User Fees. H.R. 1260 would require FDA to assess and collect application and other user fees from manufacturers of drugs for animals to expedite the development of such drugs and the review of new and supplemental animal drug applications and investigational animal drug submissions. H.R. 1260 would create four types of user fees: (1) animal drug application and supplement fees, (2) animal drug product fees, (3) animal drug establishment fees, and (4) animal drug sponsor fees. The fees could be refunded, waived, or reduced in certain situations. The aggregate amounts of such fees are specified for each of fiscal years 2004 through 2008. Each year the amounts to be collected would be adjusted further for inflation, workload estimates, and other factors, when applicable. CBO assumes FDA would collect the amounts specified in the bill increased by the inflation index for wages and salaries for federal workers. In total, we estimate receipts from those fees would amount to \$48 million over the 2004-2008 period. Such fees could be collected and made available for obligation only to the extent, and in the amount, provided in advance in appropriation acts.

Under the bill, those user fees could not be assessed in a given year unless appropriations for salaries and expenses of FDA (excluding the amount of user fees appropriated for such fiscal year) in that year satisfy a maintenance-of-effort requirement: the amount appropriated would have to exceed the amount appropriated for 2003 by the percentage increase since 2003 in the consumer price index for all urban consumers (CPI-U). In addition, fees could be collected and made available to defray increases in the cost of resources allocated to reviewing animal drug applications only to the extent that the percentage increase in those costs (excluding fees) exceeds the costs for fiscal year 2003 adjusted by CPI-U. (The bill defines special circumstances under which the Secretary would be considered to have met the maintenance-of-effort requirement.) This estimate assumes that these conditions would be met.

Before accounting for costs associated with additional administrative activities not covered by the user fees, CBO estimates that establishing the user fee program would reduce net outlays by \$2 million in 2004 and \$7 million over the 2004-2008 period, assuming appropriation of the necessary amounts. The estimated budget authority for collections and spending offset each other exactly from 2004 through 2007, while outlays would lag slightly, resulting in small savings each year. For fiscal year 2008, the bill would authorize the assessment and collection of up to three months of operating reserves for the review of animal drug applications for the first three months of fiscal year 2009. However, the user fee program is authorized only through fiscal year 2008. CBO assumes that the amounts available for obligation and spending in fiscal year 2008 would not include those special reserve funds collected in that year. The difference between the estimated collections and spending of the user fees in fiscal year 2008 would result in savings of \$3 million for that year, CBO estimates.

Other Administrative Expenses. Based on the experience with similar activities of FDA, CBO assumes that funding for certain administrative activities associated with the new user fee program would not be fully covered by the new fees. The bill would require that FDA report annually to the Congress on its performance under the user fee program and on the fiscal status of the program. H.R. 1260 also would require that FDA consult with the Congressional committees of jurisdiction and outside experts, including industry and consumer groups, and publish its recommendations concerning reauthorization of the user fee program. CBO estimates that the administrative activities associated with implementing the user fee program that are not covered by the user fees would cost about \$2 million over the 2004-2008 period.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 1260 contains no intergovernmental mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

Subject to approval in appropriation acts, H.R. 1260 would require manufacturers of new drugs for animals to pay application fees, product fees, establishment fees, and drug sponsor fees to the FDA. The application fees would apply to new or supplemental animal drug applications that are submitted after September 1, 2003. The product, establishment, and drug sponsor fees would apply to manufacturers of new animal drug products that have an application pending with the FDA after September 1, 2003. The duty to pay those fees would be a private-sector mandate under UMRA. CBO estimates that the fees collected over the 2004-2008 period would total \$48 million. Those amounts would not exceed the annual threshold specified in UMRA (\$117 million in 2003, adjusted annually for inflation) in any of the first five years that the mandates would be effective.

PREVIOUS CBO ESTIMATE

On May 15, 2003, CBO transmitted a cost estimate for S. 313, the Animal Drug User Fee Act of 2003, as ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on February 12, 2003. The two bills are nearly identical and the estimated budgetary effects are the same.

ESTIMATE PREPARED BY:

Federal Estimate: Margaret Nowak

Impact on State, Local, and Tribal Governments: Leo Lex

Impact on the Private Sector: Daniel Wilmoth

ESTIMATE APPROVED BY:

Peter H. Fontaine

Deputy Assistant Director for Budget Analysis